REMARKS

Claims 29-41, 43, 66-93, 95, 106-110, 112-125, 127-153 and 158-177 are currently pending in light of the amendments above. Claims 44 and 154-157 have been canceled without prejudice or disclaimer. Claims 66, 69, 72-74, 121, 136 and 145 have been amended and claims 158-177 have been added. The claims and are completely supported by the specification as filed and no new matter has been introduced.

I. Objection to Claim 44

The Examiner maintains the objection to Claim 44 as allegedly reciting an improper Markush Group. *See,* Paper No. 15, page 2-3 and Paper No. 22, page 2, paragraph no. 4. In particular, the Examiner states at page 2 of the Office Action (Paper No. 22):

> 'unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility'.... Applicant urges that all of the compounds recited in the Markush group share the common structural feature of being polynucleotides and that they have a common utility because each of them can be used to detect a polynucleotide encoding SEQ ID NO:2 in a sample. This argument is not persuasive because the common structural feature does not serve as a basis for the common utility.

Applicants respectfully disagree, but solely in the interest of facilitating prosecution, Applicants have canceled claim 44 and consequently submitted new claims 158-177, thereby obviating the objection. Applicants respectfully request that the objection to claim 44 as being an allegedly improper Markush group be withdrawn.

II. Objection to Claims 154-157 Under 37 C.F.R. § 1.75(c)

Claims 154-157 are objected to under 37 C.F.R. § 1.75(c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. *See,* Paper No. 22, page 3, paragraph no. 5.

Applicants respectfully disagree, but solely in the interest of facilitating prosecution, Applicants have canceled claims 154-157, therefore, the rejection is moot.

Accordingly, Applicants respectfully request that the objection to claims 154-157 be withdrawn.

III. The Claimed Subject Matter Has Utility Under 35 U.S.C. §§ 101 And 112

The Examiner has rejected claims 29-41, 43-93, 95, 106-110, 112-125, and 127-157 under 35 U.S.C. § 101 because the claims are allegedly drawn to an invention with no apparent or disclosed specific and substantial credible utility. More particularly, the Examiner states at pages 3-4, paragraph no. 6 of the Office Action (Paper No. 22):

> Applicant has traversed this rejection on the premise that the polypeptides of the instant invention are useful 'as a cancer diagnostic and/or therapeutic.' This assertion is not credible because it is unsupported by either evidence of the involvement of a protein of the instant invention in any particular oncogenic process or scientific reasoning which would support such a conclusion. At best, Applicant has shown that the overexpression of the 'galectin 11' protein in a host cell is toxic to that cell because it induces apoptosis....there is no evidence of record which supports a conclusion that the galectin 11 polypeptide of the instant invention is differentially expressed in any cancer....Because the instant specification provides no evidence that galectin 11 is differentially expressed in a cancer then that artisan would not have a reasonable expectation of successfully identifying such a cancer.

Applicants respectfully disagree and traverse this rejection.

Preliminarily, Applicants respectfully point to the M.P.E.P § 2107 (II)(B)(1), which states (emphasis added):

> If the applicant has asserted that the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art, do not impose a rejection based on lack of utility....
> Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. An applicant need only provide *one* credible assertion of specific and substantial utility for each claimed invention to satisfy the utility requirement.

The burden is on the Examiner to establish that it is more likely than not that a person of ordinary skill in the art would not consider the utility asserted by Applicants to be

specific, substantial, and credible. *See* M.P.E.P. § 2107 at 2100-30. Thus, the Examiner must provide evidence sufficient to show that the statement of asserted utility would be considered "false" by a person of ordinary skill in the art. *Id.* at 2100-40. The Examiner must also present countervailing facts and reasoning sufficient to establish that a person of ordinary skill would not believe the Applicants' assertion of utility. *See Id.*; *see also, In re Brana,* 51 F.3d 1560, 34 U.S.P.Q.2d 1436 (Fed. Cir. 1995). For the reasons set forth below, the Examiner has not met the burden that is necessary to establish and maintain a rejection for lack of utility under 35 U.S.C. § 101.

The Examiner has provided no evidence that (1) the logic underlying Applicants' assertions of utility is seriously flawed, (2) the facts upon which Applicants base the assertions of utility are inconsistent with the logic underlying the assertions, or that (3) the statements of asserted utility in the present application would be considered "false" by a person of ordinary skill in the art.

As shown above, the Examiner alleges that Applicants' assertion that the claimed invention is useful as a cancer diagnostic and/or therapeutic is not credible. In support of this conclusion, the Examiner contends that the assertion of utility is not supported by evidence of the involvement of a protein of the invention in any particular oncogenic process or scientific reasoning which would support such a conclusion. As discussed below, contrary to the Examiner's allegations, Applicants have indeed provided evidence and scientific reasoning that would lead one of ordinary skill in the art to conclude that Applicants' asserted utility of the invention is credible. For example, the specification asserts at, page 1, lines 16-19; page 4, lines 10-12; page 34, line 10 to page 35, line 16; page 35, lines 28-32; page 40, line 26 to page 41, line 7; page 41, line 32 to page 42, line 22; page 45, lines 7-14; and Example 5, that the polypeptides of the invention are useful, for example, as a diagnostic and/or therapeutic of cancer and autoimmune diseases. The specification also clearly describes *in vitro* data that supports the asserted utilities. For example, the specification discloses at page 63, line 10 to page 65, line 5 and Figures 5A-B that transfection of a constitutive galectin-11 expression construct into human Jurkat T-cells induces apoptosis of the transfected cells. According to M.P.E.P § 2107.03 (I) at 2100-43:

> evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. *Cross v. Izuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); *Nelson v. Bowler*, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An application can establish a reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence...or any combination thereof.

Moreover, M.P.E.P (III) at 2100-44 (emphasis added) states that:

> [i]f reasonably correlated to a particular therapeutic or pharmacological utility, data generated using *in vitro* assays, or from testing in an animal model or a combination thereof almost invariably will be sufficient to establish therapeutic or pharmacological utility for a compound, composition, or process.... If an applicant provides data, whether from *in vitro* assays, or animal testing or both, to support an asserted utility, and an explanation of why that data supports the asserted utility, the Office will determine if the data would be viewed by one skilled in the art as being reasonably predictive of the asserted utility.

Therefore, there is no need to prove that a correlation exists between a particular activity and an asserted diagnostic or therapeutic use of a compound as a matter of statistical certainty or provide actual evidence of success in treating humans where such a utility is asserted. M.P.E.P. §§ 2107.01 to 2107.03. All that is required of Applicants is that there be a reasonable correlation between the biological activity and the asserted utility. *See Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980); M.P.E.P. §§ 2107.01 to 2107.03. The observation that constitutive expression of galectin-11 in human Jurkat T-cells induces apoptosis of the transfected cells is reasonably predictive that the claimed polypeptides are useful in diagnosing and/or therapeutic treatment of pathological conditions such as cancer and autoimmune diseases, particularly autoimmune diseases where inhibiting T cell activation by triggering apoptosis would be beneficial (See, specification at page 40, line 26 to page 41, line 7). Additionally, Applicants submitted evidence in their response dated March 30, 2001 as Exhibit A (PCT publication WO 00/63221), which provides further support for Applicants' asserted utilities. For example, at page 280, line 16 to page 281, line 28, *in vitro* data is discussed which demonstrates that Galectin-11 polynucleotides possess cell cycle arrest activity. It is well known in the art that cell

cycle arrest can trigger premature apoptosis. Thus, evidence has been shown which demonstrates that polynucleotides of the invention can both induce apoptosis of human T cells and cause cell cycle arrest. This evidence is reasonably predictive that the claimed polypeptides are useful in diagnosing and/or therapeutic treatment of pathological conditions such as cancer and autoimmune diseases. Accordingly, these data clearly comport with Applicants' asserted utilities and one of ordinary skill in the art would consider Applicant's asserted utility of the invention to be credible and clearly would have no basis for considering this asserted utility to be "false."

In addition, the Examiner states at page 4 of the Office Action:

> there is no evidence of record which supports a conclusion that the galectin 11 polypeptide of the instant invention is differentially expressed in any cancer....Because the instant specification provides no evidence that galectin 11 is differentially expressed in a cancer then that artisan would not have a reasonable expectation of successfully identifying such a cancer

Applicants respectfully point out that they are not required to provide evidence that the claimed polynucleotides of the invention are differentially expressed in any particular cancer in order to satisfy the utility requirements under 35 U.S.C. § 101. All that is required of Applicants is that there be a reasonable correlation between the biological activity and the asserted utility. *See Nelson v. Bowler*, 626 F.2d 853, 857 (C.C.P.A. 1980); M.P.E.P. §§ 2107.01 to 2107.03. As mentioned above, evidence provided by Applicants (and the record as a whole) is reasonably predictive that the claimed polypeptides are useful in diagnosing and/or therapeutic treatment of pathological conditions such as cancer and autoimmune diseases and the observed biological activities shown by Applicants are reasonably correlated with said utility.

Thus, for the reasons stated above, the utilities asserted in the specification for the Galectin-11 polynucleotides of the present invention are indeed specific, substantial and credible. Accordingly, Applicants respectfully request that the rejection of claims 29-41, 43-93, 95, 106-110, 112-125, and 127-157 under 35 U.S.C. § 101 be reconsidered and withdrawn.

The Examiner has rejected claims 29-41, 43-93, 95, 106-110, 112-125, and 127-157 under 35 U.S.C. 112, first paragraph, as allegedly failing to adequately teach how to use the instant invention. See Paper No. 22, page 5, paragraph no. 7.

For the reasons discussed above in response to the rejection under 35 U.S.C. §101, the claimed invention is supported by a specific, substantial and credible asserted utility. The Examiner "should not impose a 35 U.S.C. §112, first paragraph, rejection grounded on a 'lack of utility' basis unless a 35 U.S.C. §101 rejection is proper." M.P.E.P. §2107 (IV) at 2100-36. Therefore, because the claimed invention complies with the utility requirement of 35 U.S.C. §101, the rejections under 35 U.S.C. §112, first paragraph, based on the alleged lack of utility of the claimed invention, should be withdrawn. Accordingly, Applicants respectfully request that the rejections of claims 29-41, 43-93, 95, 106-110, 112-125, and 127-157 under 35 U.S.C. §112, first paragraph, be reconsidered and withdrawn.

IV. Claim Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 136, 145 and 154-157 have been rejected under 35 U.S.C. § 112, second paragraph (*See*, Paper No.22, page 5, paragraph no. 8), as allegedly being indefinite for failing to particularly point out and claim the subject matter which the applicant regards as the invention.

In particular, the Examiner alleges:

> there is no antecedent basis for 'a polypeptide encoded by.' The term 'amino acid sequence' in claim 121 does not serve as a proper antecedent basis for 'a polypeptide encoded by' in these claims.

Applicants have canceled claim 154-157 rendering the rejection of claims 154-157 moot. Applicants have amended claims 121, 136 and 145 thereby obviating the rejection as to claims 136 and 145. Therefore, Applicants respectfully request that the Examiner withdraw the rejection to claims 136, 145 and 154-157 under 35 U.S.C. § 112, second paragraph.

Conclusion

Applicants respectfully request that the amendments and remarks above be entered and made of record in the file history of the instant application. Applicants believe that the application is now in condition for allowance and a notice to that effect is earnestly solicited.

If there are any additional fees due in connection with the filing of this paper, please charge the fees to our Deposit Account No. 08-3425. If a fee is required for an

extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

Dated: JANUARY 14, 2002

Jonathan L. Klein (Reg. No. 41,119)
Attorney for Applicants

Human Genome Sciences, Inc.
9410 Key West Avenue
Rockville, MD 20850
(301) 251-6015 (phone)

JKE/SA/vr